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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,472	03/09/2001	Alan R. Brooks	015303-000510US	7251

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EXAMINER

STEADMAN, DAVID J

ART UNIT PAPER NUMBER

1652

DATE MAILED: 06/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/803,472

Applicant(s)

BROOKS ET AL.

Examiner

David J. Steadman

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Application Status

- [1] Claims 1-29 are pending in the application.
- [2] Applicant's amendments to the specification in Paper No. 5, filed August 30, 2001, and Paper No. 11, filed January 30, 2003, are acknowledged.
- [3] Receipt of an Information Disclosure Statement (Form PTO-1449) filed as Paper No. 12 is acknowledged. The cited references will be considered and a copy of Form PTO-1449 will be returned in a subsequent Office action.

Election/Restrictions

- [4] Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claim(s) 1-6, drawn to an isolated nucleic acid, an expression cassette, and an isolated eukaryotic cell comprising said expression cassette, classified in class 435, subclass 325.
 - II. Claim(s) 7 and 8, drawn to an isolated protein, classified in class 530, subclass 350.
 - III. Claim(s) 9, drawn to an antibody, classified in class 530, subclass 387.9.
 - IV. Claim(s) 10-18, drawn to a method of modulating estrogen signaling, classified in class 435, subclass 6.
 - V. Claim(s) 19-26, drawn to a method of detecting the presence of estrogen signaling, classified in class 435, subclass 6.
 - VI. Claim(s) 27-29, drawn to a method of identifying a compound capable of acting as an estrogen receptor agonist or antagonist, classified in class 435, subclass 7.1.
- [5] The inventions are distinct, each from the other because:
- [6] The nucleic acid of Group(s) I, the polypeptide(s) of Group(s) II, and the antibody of Group(s) III each comprises a chemically unrelated structure capable of separate manufacture, use, and effect. The polynucleotide(s) of Group(s) I has other utility besides encoding polypeptides such as being used as a hybridization probe, the polypeptide(s) of Group(s) II can be made by another method such as

purification from the natural source or chemical synthesis, and the antibody of Group(s) III can be made by a protein other than the polypeptide(s) of Group(s) II such as a polypeptide purified from the natural source or made by chemical synthesis.

[7] The polynucleotide(s) of Group(s) I and the methods of Groups IV-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide(s) of Group(s) I can be used for protein expression.

[8] The polypeptide(s) of Group(s) II is unrelated to the method(s) of Group(s) IV and V as it is neither used nor made by the method(s) of Group(s) IV and V.

[9] The polypeptide(s) of Group(s) II and the method of Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide(s) of Group(s) II can be used as an antigen in the production of the antibody of Group III.

[10] The antibody of Group(s) III is unrelated to the method(s) of Group(s) IV-VI as it is neither used nor made by the method(s) of Group(s) IV-VI.

[11] The methods of Groups IV-VI are independent as they comprise different steps, utilize different products and yield different results.

[12] MPEP § 803 sets forth two criteria for restricting between patentably distinct inventions – 1) the inventions must be independent or distinct and 2) there must be a serious burden on the examiner. MPEP § 803 states, "For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02". Because the inventions of

Groups I-VI are distinct for the reasons given above and have separate classification and/or each of the inventions requires a separate patent and non-patent literature and/or sequence search, restriction for examination purposes is proper.

[13] A telephone call was made to Mr. Kenneth A. Weber on June 18, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

[14] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[15] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652

AS 06/19/03